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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/622,621

07/18/2003

Jan Weber

S63.2-10856-US01

2650

490 7590 12/29/2010  
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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/29/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/622,621	WEBER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	CHRISTOPHER D. KOHARSKI	3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27,28,30-38 and 63-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-38 and 68-70 is/are allowed.
- 6) ☒ Claim(s) 27,28,30,31 and 63-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07/18/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Acknowledgements***

The Examiner acknowledges the reply filed 10/26/2010 in which no claims were amended and no new claims were added. Currently claims 27-28, 30-38 and 63-70 are pending for examination in this application.

### ***Claim Rejections - 35 USC § 102e***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 65 is rejected under 35 U.S.C. 102(e) as being anticipated by Steadham et al. (USPN7,331,933). Steadham et al. discloses a balloon with compression member.

Regarding claim 65, Steadham et al. further discloses a balloon comprising a balloon body (30) having a proximal end (near 46) and a distal end (near 34), and the balloon (30) comprising circumferential elastic bands (40, 42) on the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration (col 4, ln 40-60, Figure 2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27-28 and 63-64 are rejected under 35 U.S.C 103(a) as being unpatentable over Anderson (USPN6,007,517) in view of Yang et al. (US2001/0003796).

Regarding claims 27-28 and 63-64, Anderson discloses a medical balloon (3, Figures 1A-1B) having a longitudinal axis (along tube 2) and proximal (near 4) and distal ends (near 3 the balloon (5) connecting to a coaxial shaft (4) at the proximal end thereof and connecting to the same (4) or a different coaxial shaft at the distal end thereof, and having a central body wall portion between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal (ends of balloon 3) and distal wall (ends of balloon 3) portions, respectively, wherein the balloon (3) further comprises a lumen (7) offset from the longitudinal axis (along axis of tub 2) extending

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through the tapering proximal and distal wall portions, the lumen spaced apart from the coaxial shaft at the proximal end and the coaxial shaft at the distal end (Figures 1A-3A).

Anderson meets the claim limitations as described above except for the specific balloon materials.

However, Yang et al. teaches a hydrophilic lubricity coating.

Regarding claims 27-28 and 63-64, Yang et al. teaches a balloon catheter (10, Figure 2) wherein the balloon formed of radiation cured polymerized composition ([0053]).

At the time of the invention, it would have been obvious to incorporate the hydrogel exterior coating of Yang et al. to the system of Anderson in order to increase balloon insertion and tracking within the patient by adding a lubricous exterior coating. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Yang et al. ([0001-0010]).

### ***Claim Rejections - 35 USC § 103***

Claims 66-68 are rejected under 35 U.S.C 103(a) as being unpatentable over Steadham et al. (USPN7,331,933) in view of Crocker et al. (USPN6,120,523).

Steadham meets the claim limitations as described above except for the bands being located on in the interior of the balloon and the balloon comprising a radiation cured polymer composition.

However, Crocker et al. teaches a focalized intraluminal balloon.

Regarding claims 66-68, Crocker et al. teaches a polymeric (cross-linked polyethylene, col 7, ln 35-55) balloon and is a multi-layer polymeric film (39, 36, 38, 40, 42, 44) wherein a first (36, 48) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 2-3), with a layer comprising an elastomeric band (40, 44) that is stretched during the configuration change.

At the time of the invention, it would have been obvious to change the placement of the bands and the balloon materials of Steadham in order to gain additional balloon inflation control properties and create specific inflation zones. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Crocker et al. (cols 1-2).

***Claim Rejections - 35 USC § 103***

Claims 30-31 are rejected under 35 U.S.C 103(a) as being unpatentable over Anderson (USPN6,007,517) in view of Yang et al. (US2001/0003796).

Anderson as modified by Yang et al. meets the claim limitations as described above except for the device being used in with a stent delivery catheter or with a rapid exchange catheter.

Regarding claims 30-31, it would have been obvious to use the medical balloon device as disclosed by the modified Anderson reference in combination with a stent delivery catheter or rapid exchange catheter since it well known in the medical arts to

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use stents and exchange catheter to treat body arteries and maintain vessel patency after procedures.

***Allowable Subject Matter***

Claims 32-38 and 69-70 are allowed.

***Response to Arguments***

Applicant's arguments filed 12/28/2010 have been fully considered but they are not persuasive. Applicant's Representative asserts that the combination of Anderson and Yang et al. does not disclose a medical balloon *formed of a radiation cured polymerizable composition*, and that the Steadham reference does not disclose an *elastic band having a smaller diameter than a balloon body in its at rest position*.

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Regarding the combination of Anderson in view of Yang et al., Yang et al. reference discloses a balloon element with an external coating that is formed of a radiation cured material ([0053]). The Examiner asserts that this is part of the balloon and therefore a portion of the balloon is formed of a radiation cured materials and therefore meets the claimed limitation. The Examiner acknowledges that the base layer of the balloon comprises other materials ([0019]), however the radiation cured coating is applied the balloon surface and is part of the balloon and therefore meets the claim limitation of a balloon comprising a radiation cured polymer.

Regarding the Steadham reference, the elastic bands (col 2, ln 55-65) have a diameter that is smaller than the balloon in their rest configuration (see Figure 2), i.e. the balloon is not inflated and the bands are shown at rest to have a smaller region and to compress the balloon (44) to a smaller diameter when the bands are placed. Figure 2 of the Steadham reference discloses the balloon (44) at rest, depicted are the bands (40) which (see near 46) are smaller than the rest of the balloon surface (see Figure 2, where the bands are below the respective surface of the balloon body). Therefore the Examiner considers the bands to have a smaller diameter than the balloon body since they are no over the balloon body but below the surface.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 12/28/2010

/Christopher D Koharski/  
Examiner, Art Unit 3763